

**SECTION 5: 510(k) SUMMARY**

In accordance with the requirements of 21 CFR 807.92(c) Mirador Biomedical, Inc. (hereafter "Mirador") has prepared this 510(k) Summary to provide information supporting the substantial equivalence of the Mirador Compass™.

General Information:

Date of Summary Preparation:	26 July 2011
Name and Address of Manufacturer:	Mirador Biomedical, Inc. 2815 Eastlake Ave E. Suite 220 Seattle, Washington 98102
Contact Person:	Justin Hulvershorn, MD, PhD Chief Science Officer Phone: (206) 295-3372
Trade Names:	Compass™ GP Compass™ Thoracentesis Compass™ Paracentesis Compass™ Compartment Pressure Compass™ Epidural Assist Compass™ Arterial Assist
Common Name:	Disposable Pressure Transducer
Device Classification:	Extravascular Blood Pressure Transducer Single-Function, Preprogrammed Diagnostic Computer
Classification Panel:	Cardiovascular
CFR Reference:	870.2850 870.1435
Product Code:	DRS DXG
Device Class:	Class II

Device Description: The Compass devices are disposable, point-of-use pressure measurement and monitoring devices that incorporate a pressure transducer and an integrated pre-programmed diagnostic computer with liquid crystal display (LCD). The Compass devices are designed to attach distally to an inserted needle or catheter, measure the pressure via an embedded pressure sensor, internally convert changes in pressure into electrical currents, and then display the resulting pressure via the integrated LCD.

Indications for Use: Consistent with the above device description, the Compass family of devices possesses the following indications for use:

The Compass™ GP disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Thoracentesis disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Paracentesis disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Compartment Pressure disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Epidural Assist disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Arterial Assist disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

Substantially Equivalent Predicate Devices: The Compass devices are substantially equivalent to the following legally marketed devices with respect to classification, design principles and/or indications for use:

- Compass Vascular Access – K101518 & K103715
- ReavilMED Blood Pressure Monitoring System – K101189

Device Testing: The subject Compass products are new Compass models in an existing Mirador product line of disposable pressure sensors with integrated digital displays. The new Compass device models incorporate the exact physical elements (e.g. housing, electronics) contained in the predicate Mirador products (e.g. the Compass Vascular Access that was the subject of 510(k) K101518 & K103715), except for a modified LCD display.

All packaging materials, methods and processes and the sterilization process are *identical* to the predicate Compass VA device. Therefore, all prior packaging, sterilization, and shelf life testing of the predicate Compass device remain applicable to the subject Compass devices.

With respect to device performance, given the similarities in design and mechanical operation, tests completed on the predicate Compass VA and included previously in support of predicate Mirador 510(k) K101518 and K103715 have been used to verify design requirements for the subject Compass devices. However, the subject Compass devices include a modified LCD that allows for an extended pressure range and incorporates new software. Therefore, all verification tests related to the software and pressure accuracy that were completed to support the substantial equivalence of the predicate Compass VA were re-executed for the subject Compass devices. Pressure accuracy testing was completed per ANSI/AAMI BP22:1994(R)2006.

The results from this *in vitro* testing demonstrate that the technological and performance characteristics of the Compass devices meet defined design requirements and that they can perform in a manner equivalent to devices currently on the market used for measuring physiological pressure.

Conclusion (Statement of Equivalence): The data and information presented within this submission support a determination of substantial equivalence, and therefore market clearance of the subject Compass devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

DEC 14 2011

Mirador Biomedical, Inc.
c/o Justin Hulvershorn, MD, PhD
Chief Science Officer
2815 Eastlake Ave. E., Suite 220
Seattle, WA 98102

Re: K112203

Trade/Device Names: Mirador Compass Digital Pressure Transducers consisting of the following 6 models:

- Compass™ GP
- Compass™ Thoracentesis
- Compass™ Paracentesis
- Compass™ Compartment Pressure
- Compass™ Epidural Assist
- Compass™ Arterial Assist

Regulatory Number: 21 CFR 870.2850

Regulation Name: Extravascular Blood Pressure Transducer

Regulatory Class: Class II (Two)

Product Code: DRS, DXG

Dated: November 9, 2011

Received: November 14, 2011

Dear Dr. Hulvershorn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K112203

Device Names:

Compass™ GP

Compass™ Compartment Pressure

Compass™ Thoracentesis

Compass™ Epidural Assist

Compass™ Paracentesis

Compass™ Arterial Assist

Indications for Use:

The Compass™ GP disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Thoracentesis disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Paracentesis disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Compartment Pressure disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Epidural Assist disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

The Compass™ Arterial Assist disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. [Signature]

(Division Sign-Off)

Division of Cardiovascular Devices

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Mirador Biomedical, Inc.

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